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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,332	PHILLIPS ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. This Action is in response to the communication filed on 4/22/03, as Paper No. 15. Claims 33-64 are presently pending in the application and are examined herein.

2. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 112

Claims 33-64 are rejected under 35 U.S.C. 112, first paragraph for the reasons of record. In summary, the claims are rejected because the specification, while being enabling for certain embodiments of the claim, does not reasonably provide enablement for methods inhibiting the growth of a tumor by administering a combination of a mycobacterial DNA composition (e.g., MCC, M. phlei DNA, etc.) and a chemotherapeutic agent; wherein the mycobacterial DNA composition is administered to a site other than directly into the tumor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Response to Arguments

3. Applicant's arguments filed 4/22/03 have been fully considered but they are only partially persuasive.

4. Applicants argue that the method taught by Morales is different from the claimed method because Morales teaches the administration of M. phlei cell wall (MCW) for the treatment of prostate tumors. The Applicants contend that in contrast to the method of Morales, the present application comprises administration of mycobacterial compositions (MCC, M. phlei DNA, BCC, or B-DNA) in combination with a chemotherapeutic agent. It is the Applicants position that because the claimed method is different from the method taught by Morales, the teachings of Morales cannot be applied to the present invention (See p. 8 of the response filed 4/22/03).

5. Applicants also point out that the specification provides examples of treating various types of cancer cells with the claimed compositions (See p. 8 or the response). As an example, applicants point out that data disclosed in Example 6 which demonstrates that MCC induces cell cycle arrest in methotrexate-treated Jurkat, HL-60, HL-60MX1, EL-4 and B16 cancer cells.

6. Furthermore, applicants have submitted the declaration of Mario Filion, under 37 CFR 1.132. The declaration under 37 CFR 1.132 filed 4/22/03 is insufficient to completely overcome the rejection of claims under 35 USC 112, first paragraph (enablement) as set forth in the last Office action for the reasons indicated below.

7. In response, it is respectfully pointed out that the method taught by Morales comprises administering a "fractionated and deproteinized" M. phlei cell wall complex for the treatment of prostate cancer. The fractionated and deproteinized M. phlei cell wall complex comprises M. phlei DNA, which applicants have shown is the therapeutic component of the complex. Morales, as indicated in the previous Office Action, teaches that there are a number of specific problems with respect to the M. phlei complex as a therapeutic agent. Specifically, Morales teaches that

not all administrations of the M. phlei complex are effective treatments. For instance, as was previously pointed out, Morales teaches that although administration of M. phlei complex by intratumoral administration results in regression of established prostate tumors, "the response, however, depends initially on the route of administration." "The intraperitoneal route was found to be not only in effective, but detrimental." (See p. 1709, bottom, first column). Furthermore, Morales teaches, "the intraperitoneal administration of MCW did not alter tumor-growth kinetics... the rats receiving MCW by this routs became lethargic, anorexic and exhibited considerable hair loss." (See p. 1707, middle of first column). Therefore, the teachings of Morales would indicate to a skilled artisan that therapeutic Mycobacterial cell wall compositions (including MCC, BCC, M. phlei DNA, and B-DNA) would not be effective if the compositions were administered by any means other than direct administration to the tumor.

8. It is acknowledged that the claimed method comprises administration of a mycobacterial composition AND a chemotherapeutic agent, which is different from the method taught by Morales. However, the instant disclosure has not provided any evidence which indicates that the mycobacterial composition could be administered by any means (e.g., systemic administration, peritoneal administration, etc.) and result in an effective treatment, even when administered in combination with a chemotherapeutic compound. Without evidence that the mycobacterial composition can be administered to a site other than directly to the tumor and result in the inhibition of tumor growth, additional experimentation would be required for one of ordinary skill in the art to be able to practice the claimed invention as a combination method.

9. Regarding the applicants arguments and the Declaration of Dr. Filion under 37 CFR 1.132, regarding the treatment of cancer cell types other than melanoma, it is acknowledged that

the specification and Declaration indicate that MCC can be used to inhibit the growth of several different types of tumors when used in combination with a chemotherapeutic agent, and that the MCC and chemotherapeutic compound have a synergistic effect on tumor cell growth when used in combination. However, the examples indicate that the different cancer cell types were treated with the combination of compounds in vitro, not in vivo. The in vitro evidence presented only correlates to methods wherein the therapeutic compounds are directly administered to the tumor cells, and cannot be correlated to other types of administration (such as systemic administration of the compounds). Therefore, although the Applicants arguments and the Declaration are persuasive with respect to the treatment of tumor cells other than melanoma cells, the arguments and Declaration is not persuasive with respect to the method wherein the mycobacterial complex is administered by any means other than direct administration to the tumor.

10. In conclusion, applicants arguments have been persuasive to the point the specification while being enabling for:

A method of inhibiting tumor cell growth comprising administering to a tumor-bearing subject:

(a) a composition comprising MCC, M. phlei DNA, BCC, or B-DNA and a pharmaceutically acceptable carrier; and

(b) a chemotherapeutic agent,

wherein said composition comprising MCC, M. phlei, BCC or B-DNA and a pharmaceutical carrier is administered directly to said tumor, and wherein said composition and said chemotherapeutic agent have a synergistic effect on inhibiting tumor cell growth in said tumor bearing subject,

does not provide enablement for the full scope encompassed by the claims. Specifically, the claims are not enabled for treating tumors using a method comprising administering a composition comprising MCC, M. phlei DNA, BCC, or B-DNA wherein the composition is administered by any means other than directly to the tumor.

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
June 28, 2003

DAVET NGUYEN
PRIMARY EXAMINER